May, 2014

Calibration and Preventative Maintenance Requirements: for the Angel Concentrated Platelet Rich Plasma (cPRP) System

Dear Angel Customer:

The Angel System was designed for minimal preventative maintenance and for the elimination of calibration of any active components within the system. The active components of this device include the LED's in the fluid sensor, the centrifuge drive, the fluid pump drive and the valve assembly drive.

- The **LED's** in the fluid sensor are automatically adjusted for the correct relative intensity for each new disposable processing set prior to the initiation of each processing cycle. If an LED fails to meet specification the Angel machine will produce a Light Sensor Calibration failure alarm and will not allow processing. This alarm is described in section 5-2 of the Angel operator's manual.

- The **Centrifuge Drive** is constantly monitored for the correct centrifuge speed during operation. If the centrifuge drive fails to meet specifications the machine will alarm, shut down the centrifuge drive, and produce either an Over Speed or an Under Speed alarm. This alarm is described in section 5-3 of the Angel operator's manual. The centrifuge motor for this machine is a brushless DC motor that eliminates the need for replacement brushes, extending the life of the centrifuge drive.

- The **Fluid Pump Drive** is constantly monitored for the correct speed during operation. If the pump drive fails to meet specification the machine will alarm, shut down the pump drive, and produce either an Over Speed or an Under Speed alarm. This alarm is also described in section 5-3 of the Angel operator's manual.

- The **Valve Assembly Drive** is monitored for valve position during operation. If the valve fails to achieve specification before the pump is operated, the valve position error alarm is displayed and the processing cycle is stopped. The alarm is described in section 5-2 of the Angel operator's manual.

Based on the internal system monitoring of each active component that occurs before and during each processing cycle, calibration of these active components are not required.

Preventative maintenance of the Angel machine is described in the Angel operator's manual in section 6-7. This section describes the routine cleaning and visual inspection of the device prior to operation. Electrical checks for leakage current for this device are also described in section 1-5 of the Angel operator's manual.

Should you require further assistance, please contact your Arthrex Customer Service Representative or the Arthrex Customer Service Response Center:
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